Influence of Paravertebral Muscle Quality on Treatment Efficacy of Epidural Steroid Infiltration or Surgical Decompression in Lumbar Spinal Stenosis - Analysis of the Lumbar Spinal Outcome Study (LSOS) Data - A Swiss Prospective Multi-Center Cohort Study

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Influence of paravertebral muscle quality on treatment efficacy of epidural steroid infiltration or surgical decompression in lumbar spinal stenosis – Analysis of the Lumbar Spinal Outcome Study (LSOS) data - a Swiss prospective multi-center cohort study

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Abstract

Study design: Prospective multi-center cohort study.

Objective: To study the question whetherparavertebral muscle qualitymay affect the clinical outcome of epidural steroid infiltration (ESI) or surgical decompression in patients with symptomatic lumbar spinal stenosis (LSS).

Summary of Background Data: To the present, the impact of paravertebral muscle quality on clinical outcome of epidural steroid infiltration (ESI) or surgical decompression in patients with lumbar spinal stenosis (LSS) has not been clarified.

Methods: The Lumbar Stenosis Outcome Study (LSOS) was used as database. Patients with symptomatic LSS who received an epidural steroid infiltration (group I) or lumbar decompression surgery (group II), had a follow up of at least 12 months and a pre-treatment lumbar MRI were included (n=205). Paravertebral muscle quality was quantified by the degree of fatty degeneration (according to Goutallier) on the level L3. Clinical outcome was assessed using the Spinal Stenosis Measure (SSM), Numeric Rating Scale (NRS), Roland and Morris Disability Questionnaire (RMDQ) and EQ-5D-3Lsum score. Re-infiltration, surgery following infiltration, or revision was defined as treatment failure.

Results: ESI (group I) and surgical treatment (group II) was associated with a failure rate of 60% and 12.7%, respectively. In group I, there was a tendencyfor the rate of re-intervention to be less in patients with bad muscle quality (p=0.22). In group II, improvements in the clinical outcomes up to 12 months did not differ between Goutallier stage ≤ 1 and ≥ 2. Patients with Goutallier stage ≤ 1 had more improvement in SSM symptoms (p=0.04).

Conclusions: Relevant fatty degeneration of the paravertebral musculature, as a sign of low muscle quality, has low impact on clinical outcome and the high failure rates with conservative treatment by epidural steroid infiltration compared to surgical decompression. Therefore fatty degeneration has no relevant prognostic value for lumbar spinal stenosis treatment.

Key Words: paravertebral muscle quality, impact, lumbar spinal stenosis, clinical outcome, decompression surgery, epidural steroid infiltration

Level of Evidence: 2

INTRODUCTION

Lumbar spinal stenosis (LSS) is one of the most commonly diagnosed and treated pathologies of the spine. In the general population the prevalence of absolute and relative degenerative LSS is 22.5% and 7.3% respectively and increases with age.(1)

Epidural steroid infiltration (ESI) and surgical decompression with or without fusion are established treatment options for symptomatic lumbar spinal stenosis (LSS).Results about efficiency of ESI are mixed. In some studies, a short term benefit could be confirmed, however most studies evaluating the long term benefit did not show superior outcome compared with physical therapy.[(2)(3)(4)(5)(6)(7)(8)(9)(10)(11)]The long term success of surgical treatment varies between 45% and 72%.(12)A lower self-rated preoperative health-status, comorbidity, depression and limited, preoperative walking ability were identified as strong predictors of an unfavorable clinical outcome.(12)(13)(14)

In 2010 the lumbar spinal stenosis study was launched with the aim to identify indicators predicting the future course of patients with lumbar spinal stenosis.(15)

It seems obvious that the quality of paravertebral musculature, which represents an important support of the spinal column, would affect the outcome of LSS treatment. Dohzono et al recently showed an association between paravertebral muscle degeneration and the amount of sagittal imbalancewith low back pain.(16)(17) Further, the paravertebral muscles are innervated by dorsal branches of the spinal nerve roots. A causal relation between nerve fiber compression as it occurs in spinal stenosis, and alteration of the paravertebral muscles is plausible. (18)In considering these aspects we raised the question whether muscle quality, as reflected by fatty degeneration of the lumbar paravertebral musculature, may affect the clinical outcome and failure rate of epidural steroid infiltration or surgical decompression.

MATERIALS AND METHODS

Patient Selection and treatment strategies

The Swiss lumbar stenosis outcome study (LSOS), which is a prospective multicenter cohort study of patients with symptomatic degenerative lumbar spinal stenosis, was used as database (2010-2015). (15)The study was approved by the local ethical committee and conducted in accordance with the Declaration of Helsinki. All patients received written or oral information about the study and gave their written informed consent to participate. Patients with symptomatic LSS who received an epidural steroid infiltration (ESI, group I, n=40) or lumbar decompression surgery (Decompression, group II, n=165), who had a follow up of at least 12 months and a pre-treatment lumbar MRI were included (total n=205). Patients with evidence of stenosis caused by tumor, fracture, infection or significant deformity or any previous spinal surgeries were not included into the cohort.

ESI was performed using contrast-enhanced fluoroscopy or CT-scan for guidance. Surgical decompression was performed with a standard open or microscopic posterior lumbar laminectomy or laminectomies. Fusion by pedicle screws with rods and intersomatic fusion and cage implantation was performed as revision for failed decompression surgery in cases of significant lumbar back pain or segmental instability.

Re-infiltration, surgery following infiltration or revision surgery at the diseased segment was defined as treatment failure (Figure 1).

Image analysis and assessment of paravertebral muscle quality

MR imaging was performed in all patients included in the LSOS study. Due to the nature of a multicenter study, imaging was performed on different MRI scanners with field strengths at 1.5 and 3 T with varying scanning parameters. All imaging data from the participating clinical centers were collected at one place and therefore, saved on the picture archiving and communication system (PACS, IMPAX 6; AGFA Healthcare, Mortsel, Belgium) of the University hospital of city blinded for review process. (19)

Two fellowship-trained musculoskeletal radiologists with 8 and 26 years of experience, who were blinded to clinical information and the results of the second reader, performed image analysis. Both radiologists had remote access to the PACS system and worked independently from different cities.(19)

Paravertebral muscle quality was determined at baseline and quantified by the degree of fatty degeneration on axial T2 weighted MR images on the level L3 according to the Goutallier/Fuchs classification system (20)(21): 0 = normal, no fatty streaks, 1 = some fatty streaks, 2 = important fatty streaks, but still more muscle than fat, 3 = as much fat as muscle, or 4 = more fat than muscle. Example images for fatty atrophy are provided in Figure 2A-E. Intra- and inter-reader agreement for determining fatty degeneration was 0.87 and 0.45, respectively, and was reported in a former study by Winklhofer et al.(19)

Clinical assessment

Clinical outcome was assessed at baseline and at 12 months using the Spinal Stenosis Measure (SSM),Numeric Rating Scale (NRS), Roland and Morris Disability Questionnaire (RMDQ), EQ-5D-3Lsum score and Cumulative Illness Rating Scale (CIRS). Data were in part interview-administered and recorded by a study coordinator. All other questionnaires were self-administered and filled in by the patients themselves.

The SSM, an instrument specifically developed for spinal stenosis patients by Stucki et al.(22), targets to measure severity of symptoms and quantifies disability of the lumbar spinal stenosis population. It was already used in different studies on lumbar spinal stenosis(23)(24)(25)(26)and consists of three different subscales; the symptom severity subscale, the physical function subscale and the satisfaction subscale. The symptom severity scale can be divided into a pain domain (severity, frequency and back pain) and a neuroischemic domain (leg pain, weakness, numbness and balance disturbance). Score range is from 1-5 and 1-4 (best-worst).

The NRS serves for general assessment of lumbar spinal stenosis symptoms such as lower extremity pain and discomfort with ascore range from 0-10 (best-worst).

The RMDQ is a back pain specific, self-rated physical disability questionnaire developed by Roland and Morris in 1983.(27)Disability is measured respective to the following categories: physical function activities and activities of daily living including eating and sleeping with a score range from 0-24 (best-worst).

The EQ-5D-3L is an assessment tool to measure health-related quality of life. It measures general non-disease specific health-related quality of life, including physical, mental and social dimensions.(28) The health status measures five dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) which can be calculated as a sum score (score range 0-100, worst-best).(28)The second part of the questionnaire estimates patient's actual health status (score range 0-100, worst-best).

The CIRS documents the presence and severity of comorbid diseases in 14 organ systems (according to a modified version by Miller et al.(29)) with a range from 0-56 (best-worst). The musculoskeletal organ system was separately included in the analysis.

Minimal clinically important difference (MCID)

The MCID is defined as "the smallest difference in a score that is considered to be worthwhile or important".(30)Thus, the MCID is a threshold for a relevant change in an outcome measure. Patients who reached or even exceed this threshold consider this change as meaningful and worthwhile. According to Stucki et al.(22), MCID for SSM is reached when "Symptom Severity scale" improves at least 0.48 points and "Physical Function scale" at least 0.52 points at follow-up.

The primary outcome of the study was defined as changes in SSM symptoms and function. Secondary outcomes included MCID in SSM symptoms and function, and changes in NRS, EQ-5D-3L, and RMDQ. Further secondary outcome was the need for re-intervention (failure rate).

Statistical Analyses

All data were stored in a purpose-built database (Filemaker Pro 11, 2010; FileMaker Inc., Santa Clara, CA). Analysis of data consisted of descriptive statistics of patient demographics at baseline. Continuous variables were shown as mean and standard deviation, and categorical variables were shown as numbers and percentages of total, stratified by patients undergoing epidural infiltration (ESI, group I) or surgical treatment (group II), respectively. The non-parametric Wilcoxon test was used to compare changes in outcomes across Goutallier classification (≤ 1 / ≥ 2). To assess whether treatment failure was associated with the Goutallier classification, the chi-squared test was used. Logistic regression was used to model MCID in SSM symptoms and SSM function, depending on Goutallier classification, age and treatment (surgical therapy versus epidural infiltration). Results were presented as odds ratios (OR) and confidence intervals (CI).

The level of significance was set to $\alpha = 0.05$. All analyses were conducted with R for Windows. (R Core Team (2014). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/.)

RESULTS

In this study, 205 patients were included; 40 patients were treated by epidural steroid infiltration (group I, ESI), 165 patients underwent decompression surgery (group II, decompression surgery). Operated levels were mainly L4/5 (42%), L3/4(35%) and L2/3 (13%), 109 patients (66%) underwent multi-level decompression. Baseline characteristics forage, gender and CIRS are presented in Table 1 and were comparable in both groups.

In group I (ESI), 21 patients (52.5%) presented with good paravertebral muscle quality as defined by a Goutallier stage ≤1. Fatty degeneration stages ≥ 2 were found in 19 patients (47.5%). Reinfiltration or surgery following infiltration was necessary in 24 patients which corresponds to a failure rate of 60%. There was a tendency, though not significant, for the rate of re-intervention to be less in patients withbad muscle quality (Figure 1). The corresponding p-value of the chi-squared test was 0.22.

In group II (Decompression), 112 patients (67.9%) presented with good paravertebral muscle quality (Goutallier stage ≤ 1) whereas fatty degeneration stages ≥ 2 were observed in 53 patients (32.1%). 21 patients underwent reinfiltration or revision surgery which corresponds to a failure rate of 12.7%. There was no difference between patients with good or bad muscle quality (Figure 1). The corresponding p-value of the chi-squared test was 0.81.

There was a tendency towards better clinical outcomes (SSM subscales, NRS, RMDQ and EQ-5D-3L) in terms of improvement between baseline and 12 months follow-up in patients with Goutallier stage ≤ 1 as compared to Goutallier stage ≥ 2 (Table 2 and 3). However, these improvements did not differ significantly, except for SSM symptoms (p=0.04) in group II.

Multiple logistic regression models were fitted to MCID in SSM symptoms and SSM function at 12 months. Results of the logistics regression models revealed that Goutallier ≥ 2 was associated with significantly lower chances for MCID in SSM symptoms (OR=0.47, 95% CI 0.25 to 0.88, p= 0.02). In the corresponding model for MCID in SSM function, the estimated OR was 0.85, however, the result was not statistically significant (p=0.61).Decompression surgery was associated with higher chances of MCID for SSM symptoms (OR = 1.34, 95% CI 0.64 to 2.82), and for SSM function (OR = 2.96, 95% CI 1.44 to 6.10) (Table 4).

DISCUSSION

The results of our study indicate that relevant fatty degeneration of the paravertebral musculature (Goutallier stage ≥ 2), as a sign of low muscle quality, has low impact on failure rates and clinical outcomeof treatments with epidural steroid infiltration or decompression surgery. Surprisingly, Goutallier stage ≥ 2 tended to have lower rate of re-interventions in infiltrated patients, even if not reaching statistical significance. On the other hand, in both groups, Goutallier≥ 2 was associated with less postoperative improvement in most clinical scores.These findings might be due to potential limitations of the study.

First, epidural steroid infiltration addresses chemical pain mechanisms, which are independent of muscle quality. It is postulated that corticosteroids reduce inflammation either by inhibiting the synthesis or release of a number of pro-inflammatory substances or by causing a reversible local anesthetic effect.(31)(32)Modes of action of steroids include membrane stabilization, inhibition of neural peptide synthesis or action, blockade of phospholipase A_2 activity, prolonged suppression of ongoing neuronal discharge, and suppression of sensitization of dorsal horn neurons.(31)(32)

Second, a follow-up of one year might be too short to find significant impact of fatty degeneration on clinical outcomes and a longer-term follow-up might reveal statistical significances in the here documented tendencies. However, a longer follow-up would be challenged by the increasing crossover rate of conservatively treated to surgical treated patients over time. Third, the paravertebral muscle quality was measured only on the level L3. This disadvantage is mitigatedby a study conducted by Dohzono et al where in patients suffering from LSS no significant differences of fatty degeneration on different levels of the lumbar spine were observed.(16) Forth, spinopelvic parameters were not available for the evaluation of sagittal balance, which might be associated with lumbar back pain and could have introduced a bias. However, Bayerl et al showed that sagittal balance did not influence the clinical outcome of patients with lumbar spinal stenosis one year after surgical decompression.(33)Furthermore, it is well known that patients suffering from LSS lean forward to provide neural decompression by spinal canal widening in flexion.(34)Reactive improvement in the lumbar and global sagittal alignment can be induced by lumbar decompression surgery without fusion, even if sagittal imbalance exists preoperatively.(35)

The low impact of muscle quality on clinical outcome as well as failure rate is surprising as different studies have demonstrated an association between paravertebral muscle degeneration and low back pain (LBP).(36)(37)(38)

Nevertheless our results are in concordance with the study of Kalichman et al, which evaluated different features of spinal degeneration and their association with self-reported LBP. The only degenerative feature associated with self-reported LBP was spinal stenosis. Other degenerative features such as intervertebral disc degeneration, facet joint osteoarthritis, spondylolysis, spondylolisthesis and especially degeneration of the paravertebral muscles were not associated with the occurrence of LBP.(39) LBP is certainly not the only parameter determining the clinical outcome but is obviously represented in most questionnaires for clinical assessment of spinal pathologies.Furthermore the mean age of 75y (ESI) and 73y (Decompression) may reduce the impact of musculature with respect to the general lower activity level, particularly strenous activity.

Failure rate was lower in the surgical decompression group compared to the epidural steroid infiltration group and decompression surgery was associated with higher chance of MCID in SSM function. This finding is consistent with previous studies showing no relevant long-term improvement with epidural steroid infiltrations compared to physical therapy(11)(40), and the long term advantage of surgical decompression in selected patients. (41)

CONCLUSION

Relevant fatty degeneration of the paravertebral musculature, as a sign of low muscle quality, has low impact on clinical outcome and the high failure rates with conservative treatment by epidural steroid infiltration compared to surgical decompression. Therefore fatty degeneration has no relevant prognostic value for lumbar spinal stenosis treatment.

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FIGURE LEGENDS

Figure 1. Patient flow: number of eligible patients (pts.) at baseline undergoing epidural steroid infiltration (ESI) or decompression surgery, subclassified in Goutallier ≤ 1 andGoutallier ≥ 2.

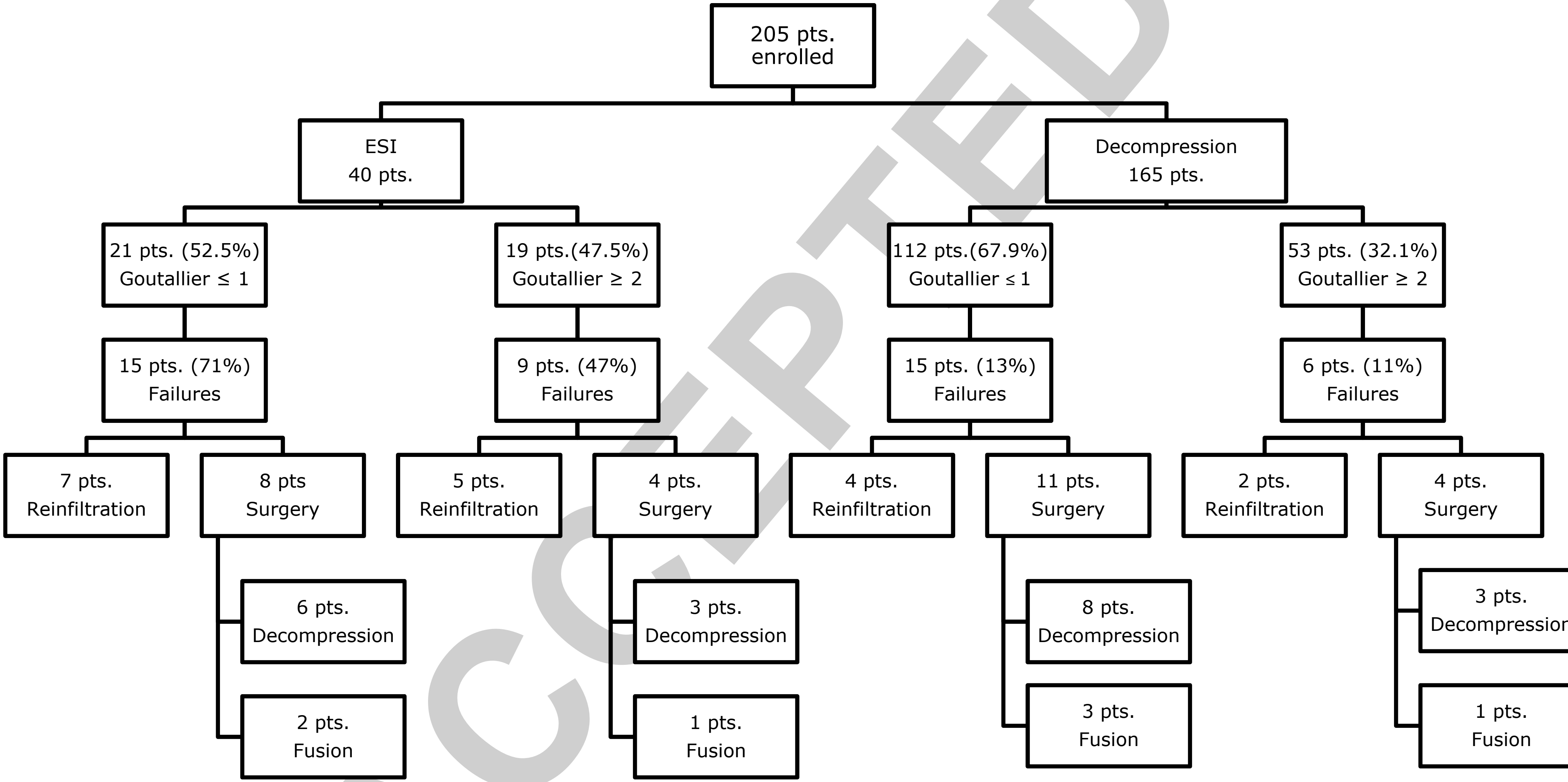
205 pts. enrolled
ESI 40 pts.
Decompression 165 pts.
21 pts. (52.5%) Goutallier ≤ 1
19 pts.(47.5%) Goutallier ≥ 2
112 pts.(67.9%) Goutallier ≤ 1
53 pts. (32.1%) Goutallier ≥ 2
15 pts. (71%) Failures
9 pts. (47%) Failures
15 pts. (13%) Failures
6 pts. (11%) Failures
7 pts. Reinfiltration
8 pts Surgery
5 pts. Reinfiltration
4 pts. Surgery
4 pts. Reinfiltration
11 pts. Surgery
2 pts. Reinfiltration
4 pts. Surgery
6 pts. Decompression
2 pts. Fusion
3 pts. Decompression
1 pts. Fusion
8 pts. Decompression
3 pts. Fusion
3 pts. Decompressior
1 pts. Fusion

Figure 1.

Figure 2. A-E. Series of axial T2 weighted MR images with increasing degree of fatty muscle degeneration at the level of L3.

A. Goutallier grade 0 = normal, no fatty streaks;

B. Goutallier grade 1 = some fatty streaks;

C. Goutallier grade 2 = important fatty streaks, but still more muscle than fat;

D. Goutallier grade 3 = as much fat as muscle;

E. Goutallier grade 4 = more fat than muscle.

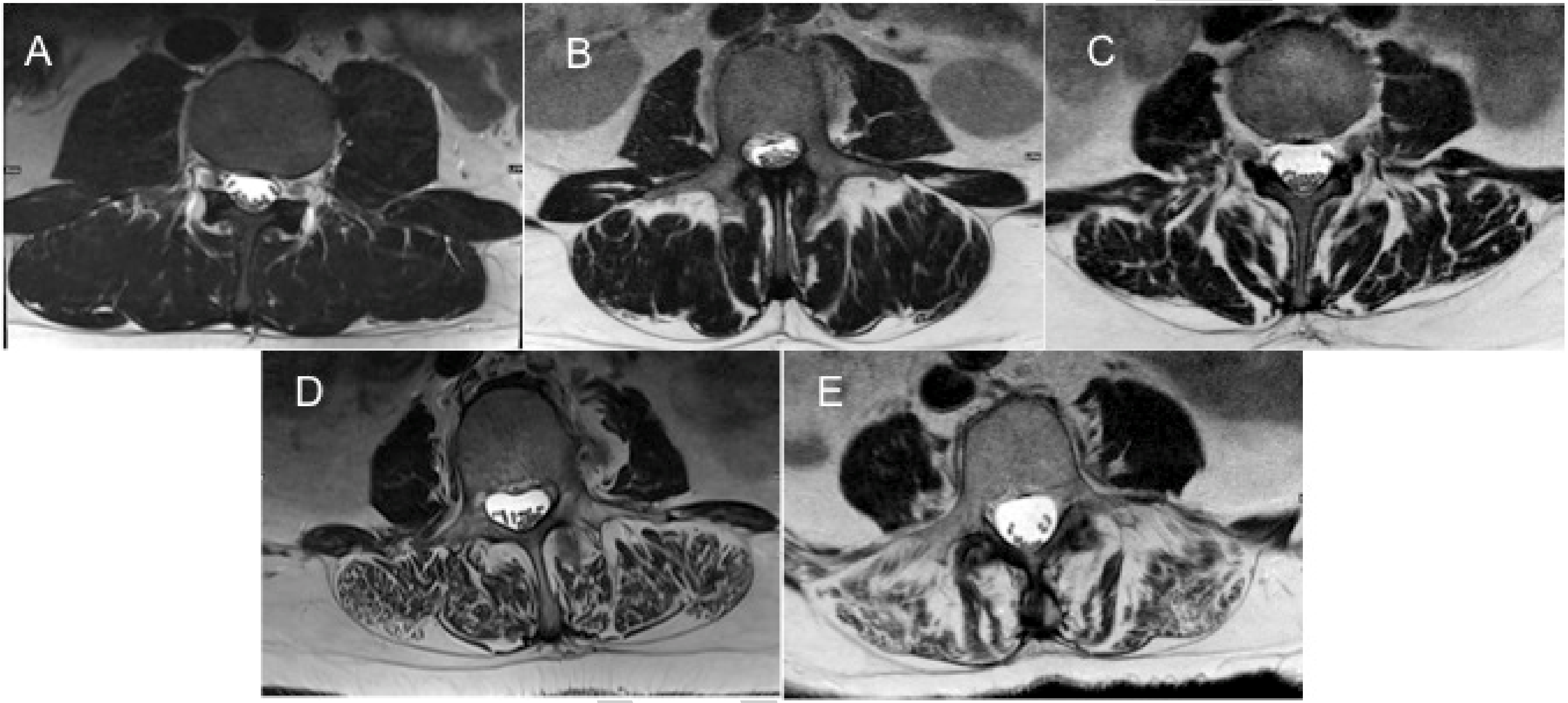

Figure 2.

TABLE 1. Patients Characteristics					
	Total Population	**ESI**		**Decompression**	
		Goutallier≤1	Goutallier≥2	Goutallier≤1	Goutallier ≥2
n (%)	205 (100)	21 (52.5)	19 (47.5)	112 (67.9)	53 (32.1)
Age, mean (sd)	74.1 (8.4)	75.0 (7.9)		73.8 (8.5)	
		73.7 (8.9)	76.5 (6.5)	72.3 (9.1)	77.0 (6.1)
Female, n (%)	112 (54.6)	21 (52.5)		91 (55.2)	
		12 (57.1)	9 (47.4)	55 (49.1)	36 (67.9)
CIRS, mean (sd)	9.1 (4.1)	8.9 (5.0)		9.1 (3.8)	
		10.4 (6.0)	7.2 (2.9)	8.7 (3.6)	10.0 (4.2)
Levels of laminectomy					
1 Level, n (%)				56 (33.9)	
				40 (24.2)	16 (9.7)
> 1 Level, n (%)				109 (66.1)	
				72 (43.6)	37 (22.4)
ESI indicates epidural steroid infiltration; CIRS cumulative illness rating scale					

TABLE 2. Differences in the Swiss SSM Scores (Mean ± SD) between baseline (T0) and 12 months follow-up (T12) in patients treated with decompression and epidural steroid infiltration (ESI) subclassified in Goutallier ≤ 1 and Goutallier ≥ 2							
ESI	Goutallier ≤ 1 (n=21)			Goutallier ≥ 2 (n=19)			p-value
	T0	T12	Improvement	T0	T12	Improvement	
SSM-symptom	3.3 (0.5)	2.6 (0.9)	0.8 (0.9)	3.4 (0.6)	2.8 (1.0)	0.6 (1.1)	0.88
SSM-function	2.4 (0.8)	1.9 (0.7)	0.5 (0.9)	2.4 (0.7)	2.0 (0.8)	0.4 (1.0)	0.83
Decompression	Goutallier ≤ 1 (n=112)			Goutallier ≥ 2 (n=53)			p-value
	T0	T12	Improvement	T0	T12	Improvement	
SSM-symptoms	3.2 (0.6)	2.1 (0.8)	1.1 (0.8)	3.2 (0.7)	2.3 (0.9)	0.8 (0.9)	0.04*
SSM-function	2.4 (0.7)	1.5 (0.6)	0.9 (0.8)	2.5 (0.7)	1.8 (0.7)	0.7 (0.8)	0.19
ESI indicates epidural steroid infiltration; SSM Spinal stenosis measure							

p-values from Wilcoxon test.

TABLE 3. Differences in the Numeric Rating Scale (NRS), Roland Morris Disability Questionnaire (RMDQ), and EQ-5D (Mean ± SD) between baseline (T0) and 12 months follow-up (T12) in patients treated with decompression and epidural steroid infiltration (ESI) subclassified in Goutallier ≤ 1 and Goutallier ≥ 2

ESI	Goutallier ≤ 1 (n=21)			Goutallier ≥ 2 (n=19)			p-value
	T0	T12	Improvement	T0	T12	Improvement	
NRS	7.5 (1.2)	4.6 (3.0)	3.0 (3.2)	6.6 (1.7)	4.1 (2.1)	2.6 (3.3)	0.88
RMDQ	12.2 (4.6)	10.4 (6.8)	1.8 (4.8)	14.8 (3.9)	10.8 (6.3)	4.0 (6.3)	0.30
EQ-5D sum score	64.3 (18.9)	74.8 (18.3)	-10.5 (24.0)	65.3 (19.8)	80.0 (16.0)	-14.7 (28.2)	0.66
Decompression	Goutallier ≤ 1 (n=112)			Goutallier ≥ 2 (n=53)			p-value
	T0	T12	Improvement	T0	T12	Improvement	
NRS	6.3 (2.2)	2.9 (2.5)	3.4 (3.1)	7.0 (2.2)	3.5 (2.5)	3.5 (3.3)	0.89
RMDQ	12.2 (5.4)	7.0 (5.6)	5.2 (5.6)	14.0 (4.8)	9.1 (6.0)	5.0 (5.7)	0.79
EQ-5D	67.4 (17.2)	84.4 (15.2)	-16.9 (19.8)	60.9 (15.7)	77.2 (16.9)	-16.2 (19.5)	0.85

ESI indicates epidural steroid infiltration

p-value from Wilcoxon test.

TABLE 4. Estimated Odds Ratios for Meaningful Improvement From a Multiple Logistic Regression Model Including Goutallier Stage, Age and Decompression Surgery				
MCID SSM Symptoms				
	Odds ratio	low95	hi95	p
(Intercept)	3.40	0.19	62.36	0.409
Goutallier≥ 2	0.47	0.25	0.88	0.019
Age	1.00	0.96	1.03	0.822
Decompression	1.34	0.64	2.82	0.434
MCID SSM Function				
	Odds ratio	low95	hi95	p
(Intercept)	2.38	0.16	36.27	0.533
Goutallier≥ 2	0.85	0.46	1.58	0.606
Age	0.98	0.95	1.02	0.345
Decompression	2.96	1.44	6.10	0.003
MCID indicates minimal clinically important difference; SSM Spinal stenosis measure				

Odds ratio for clinically meaningful improvement